

REMARKS

Upon entry of the amendment claims 44-58 will be under examination. Claims 1-43 have been withdrawn from consideration. Support for new claims 57-58 appears in the specification at, e.g., 12, lines 28-30. No new matter has been added.

Applicants have amended the specification to correct a patent number recited in the priority claim.

Rejections under 35 USC §112 second paragraph

Claims 44-56 are rejected as indefinite for not specifying the relationship between components of the kits. The rejection is traversed to the extent it is applied to the claims as amended.

Claim 44, from which depend claims 45-51, and claim 52, from which depend claims 53-56, have been amended to specify that the recited gastrin/CCK receptor ligand and EGF receptor ligand are in one container. Applicants submit that this amendment provides the requested relationship between the components of the kits and request that the rejection be withdrawn.

Claim 52 is further rejected as indefinite. Claim 52 has been amended to specify that the claimed kit comprises in a container the recited gastrin/CCK receptor ligand EGF receptor ligand, and to no longer recite an intended use.

Applicants request that the rejection be withdrawn.

Rejections under 35 USC §102(b)/103(a)

Claims 44-56 are rejected as being anticipated by, or in the alternative, as obvious over, Conteas, et al. (“Conteas”). The rejection is traversed to the extent it is applied to the claims as amended.

Claim 44, from which depend claims 45-51, requires that the gastrin/CCK receptor ligand and said EGF receptor ligand in said kit are suitable for inclusion in a pharmaceutical composition for administration to a human patient. Similarly, claim 52, from which depends claims 53-56, specifies that the recited ligands are suitable for preparing a pharmaceutical composition suitable for administration to a human patient.

There is no suggestion in Conteas of a kit including ligands that are purified enough to meet this requirement of the claims. To the contrary, Conteas is silent about kit claims and does not discuss gastrin/CCK receptor and EGF receptor ligands as components of a pharmaceutical formulations for administration to a human patient. Conteas describes instead the effects of gastrin and EGF on the rate of DNA synthesis in a small intestinal crypt cell line *in vitro*. There is no indication that the gastrin or EGF would be of any higher quality than research grade. Indeed, using gastrin and/or EGF in a form purified enough so that it is suitable for preparing a pharmaceutical composition suitable for administration to a human patient would have been extremely expensive (relative to the cost of reagent grade gastrin and EGF) and unnecessary for the experiments described in Conteas. This reference, therefore, fails to describe or suggest the claimed invention. Applicants request reconsideration and withdrawal of the rejection.

Obviousness-type Double Patenting

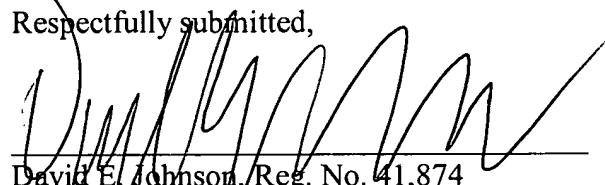
Claim 52 is rejected for double-patenting over claim 7 of US Patent No. 6,288,301. The rejection is traversed to the extent it is applied to the claims as amended.

Claim 52 has been amended so that it is drawn to a kit that includes a therapeutically effective amount of a sterile gastrin suitable for preparing a pharmaceutical composition suitable for administration to a human patient and a therapeutically effective amount of a sterile EGF 1-53 receptor ligand suitable for preparing a pharmaceutical composition suitable for administration to a human patient. The claimed kit additionally requires one or more pharmaceutically acceptable carrier or excipient capable of forming said pharmaceutical composition

Claim 7, in contrast, is not drawn to a kit but to a pharmaceutical composition. The claim specifies a pharmaceutical composition comprising a gastrin/CCK receptor ligand, an EGF receptor ligand, and a pharmaceutically acceptable carrier. There is no suggestion in claim 7, however, of a kit requiring the gastrin and EG1-53 receptor ligand species required by claim 52 of the pending application. Therefore, claim 7 of the '301 patent cannot be said to render obvious the invention of claim 52. Applicants request reconsideration and withdrawal of the rejection for obviousness-type double patenting.

Applicants submit that the claims are now in condition for allowance, and such action is respectfully requested. A petition for extension of time accompanies this response. The Commissioner is authorized to charge any fees that may be due, or credit any overpayments of same, to Deposit Account No. 50-0311, Ref. No. 24492-021.

Respectfully submitted,



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